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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/214,645	09/27/1999	JAY M. SHORT	09010/046001	8386

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EXAMINER	
SISSON, BRADLEY L	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 11/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/214,645	SHORT, JAY M.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 16-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

> To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Vas-Cath, 935 F.3d at 1563; see also Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); In re Gosteli, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572.

3. Claims 16-20 and 24-39 are drawn to a method for producing a mutagenized polynucleotide encoding a polypeptide having any desired property. Claim 22 is drawn to a

vector comprising said mutagenized polynucleotide. And claims 21 and 23 are drawn to a polypeptide that has any desired property.

4. For convenience, claims 16 and 17, the only independent claims under consideration, are reproduced below.

16. (currently amended) A method for producing a mutagenized polynucleotide encoding a polypeptide having a desired property comprising:

blocking or interrupting a polynucleotide synthesis process by contacting a polynucleotide encoding a polypeptide or regulating expression of a polypeptide, with one or more agents that block or interrupt synthesis of the polynucleotide, wherein the agent is selected from UV light, one or more DNA adducts, DNA intercalating agents, DNA binding proteins, triple helix forming agents, competing transcription polymerase, cold or heat, chain terminators, polymerase inhibitors and poisons, and

subjecting said polynucleotides to denaturation, hybridization, and elongation and ~~selection~~ to produce [[a]] mutagenized polynucleotides ~~encoding a polypeptide having the desired property~~ and,

selecting for mutagenized polynucleotides encoding polypeptides having the desired property.

17. (currently amended) A method for producing a mutagenized polynucleotide encoding a polypeptide having a desired property, said method comprising:

(a) blocking or interrupting a polynucleotide synthesis process by contacting a polynucleotide encoding a polypeptide or regulating expression of a polypeptide, with at least one agent that blocks or interrupts synthesis of the polynucleotide, wherein the agent is selected from UV light, one or more DNA adducts, DNA intercalating agents, DNA binding proteins, triple helix forming agents, competing transcription polymerase, cold or heat, chain terminators, polymerase inhibitors and polymerase poisons, to provide a plurality of single or double-stranded polynucleotides;

(b) denaturing the plurality of single or double-stranded polynucleotides to produce single-stranded polynucleotides;

(c) incubating the single-stranded polynucleotides with a polymerase under conditions which result in annealing of the single-stranded polynucleotides at regions of homology between the single-stranded polynucleotides and under conditions which promote synthesis of mutagenized polynucleotides, and;

(d) expressing at least one of the mutagenized ~~polypeptides~~ polynucleotides ~~wherein the polypeptide is identified as possessing a desired property, thereby producing a mutagenized polynucleotide encoding a polypeptide having a desired property~~ to produce a mutagenized polypeptide, and

(e) selecting said mutagenized polypeptides for the desired property in order to identify a mutagenized polynucleotide encoding a polypeptide having the desired property.

5. For purposes of examination, method claims 16-20 and 24-39 have been interpreted as encompassing a method that will result in the production of any nucleic acid that encodes any polypeptide that has virtually any property, including cures for cancer, old age, and the common cold, and where the encoding nucleic acid is produced by either a) contacting a polynucleotide encoding a polypeptide- any polypeptide, including those that bear no resemblance to the intended product, or b) regulation of any polypeptide with one or more of the following: UV light, one or more DNA adducts, DNA intercalating agents, DNA binding proteins, triple helix forming agents, competing transcription polymerase, cold or heat, chain terminators, polymerase inhibitors and poisons. Claim 22, drawn to a vector, has been interpreted as encompassing any

polynucleotide that encodes any polypeptide that has any desired property. And claims 21 and 23 have been interpreted as encompassing any polypeptide that has any desired property.

6. The specification has been found to contain the following prophetic examples:

a. Example 1, page 64, "Generation of Random Size Polynucleotides Using U.V. Induced Photoproducts;"

b. Example 2, page 64, "Isolation of Random Size Polynucleotides;"

c. Example 3, page 65, "Shuffling of Isolated Random Size 100-300bp Polynucleotides;" and

d. Example 4, pages 65-66, "Screening of Polypeptides from Shuffled Polynucleotides."

7. None of these examples resulted in the production of the claimed end product that the nucleic acid encodes a polypeptide that ahs been found to exhibit a desired property. While there is no *per se* rule that an applicant must exemplify each and every embodiment encompassed by the claims, the level of disclosure required varies inversely with the predictability of the art. Furthermore, the specification fails to provide an adequate written description of the polynucleotides encompassed by claim 22, nor does it provide an adequate written description of any polypeptide encompassed by claims 21 and 23.

8. Attention is directed to the decision of *Fiers v. Sugano* 25 USPQ2d 1604-5 (CAFC, January 1993) wherein is stated:

> We also reject *Fiers* argument that the existence of a workable method for preparing a DNA establishes conception of that material. Our statement in *Amgen* that conception may occur, *inter alia*, when one is able to define a chemical by its method of preparation requires that the DNA be claimed by its method of preparation. We recognize that, in addition to being claimable by structure or physical properties, a chemical material can be claimed by means of a process. A product-by-process claim normally is an after-the-fact

> definition, used after one has obtained a material by a particular process. Before reduction to practice, conception only of a process for making a substance, without a conception of a structural or equivalent definition of that substance, can at most constitute conception of the substance claimed as a process. Conception of a substance claimed *per se* without reference to a process requires conception of its structure, name, formula, or definitive chemical or physical properties. . .
> * * * *
> The difficulty that would arise if we were to hold that a conception occurs when one has only an idea of a compound, defining it by its hoped-for function, is that would-be inventors would file patent applications before they had made their inventions and before they could describe them. That is not consistent with the statute or the policy behind the statute, which is to promote disclosure of inventions.

Attention is also directed to the decision of *University of California v. Eli Lilly and Co.* (CA FC, July 1997) 43 USPQ2d 1398 wherein is stated:

> In claims involving chemical materials, generic formulas usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate written description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is See Fiers, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what it achieves as a result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. *See In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.
>
> Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

9. In the instant case, the specification fails to provide an adequate written description of how the specific nucleic acids are to be produced and identified. Similarly, the specification fails to provide an adequate written description of the actual polynucleotides and polypeptides that are claimed. It is note with particularity that the method is not to result in the production of simply a mutagenized polynucleotide, but rather, it is to result in the production of polynucleotides that encode a polypeptide that has any desired property, including those that have yet to be identified, and for which no screening method yet exists. Similarly, the product claims fairly encompass just such novel polynucleotides and polypeptides. The specification does not provide an adequate written description of any reproducible procedure, or of the products produced therefrom, where a specific desired property, and which has utility, has been produced.

10. In view of the tremendous breadth of scope of the claims and the limited guidance provided, the specification fails to provide an adequate written description of the claimed invention. Further, the specification fails to reasonably suggest that applicant had possession of the inventions at the time of filing.

11. Claims 1-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see

> *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

It is well settled that one cannot enable that which they do yet possess. As shown above, the specification des not reasonably suggest that applicant was in possession of the claimed method, vector, or polypeptides. Accordingly, the same specification does not enable the making and using of the full scope o the claimed invention.

12. As presented above, the specification provides four prophetic examples, none of which result in the production of any polypeptide that has a specific desired property. Further, the specification does not enable the making and use of the claimed vector or polypeptide.

13. Clearly, the claimed method, vector and polypeptide encompass that which has utility as a pharmaceutical, which is an area of art recognized as being unpredictable and deserving, therefore, of greater levels of disclosure. In support of this position attention is directed to *In re Fisher* 166 USPQ 18 (CCPA, 1970):

In cases involving predictable factors, such as that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

14. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d

1001. As set forth in the decision of the Court:

" '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').

*****

"Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.
"It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. <u>However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art.</u> It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

15. In view of the breadth of the claims, the unpredictability of the art, and the limited disclosure, the specification is deemed not to enable the full scope of the claimed invention, but rather, provides only a guide and motivation for others to further develop what applicant claims as their own. Such nondisclosure unfairly shifts the burden of enablement from applicant to the public. In order for the public to practice the full scope of the invention, one would have to resort to trial and error experimentation with little, if any reasonable expectation of success. Such effort on the part of the public constitutes undue experimentation. Accordingly, and in the absence of convincing evidence to the contrary, claims 16-39 are rejected under 35 USC 112, first paragraph, as not being enabled by the disclosure.

Response to argument

16. At page 9, bridging to page 10 of the response received 15 January 2004, hereinafter the response, argument is presented that "independent claims 16 and 17 have been amended to require only that mutagenized polynucleotides be produced and that the mutagenized polypeptides be screened for those that encode polypeptides having the desired property."

17. While agreement is reached in that claims 16 and 17 have been amended, the method claims (claims 16-20 and 24-39) all require that the method is to result in the selection of a polynucleotide that encodes a polypeptide that has any desired property. As presented above, such breadth of scope fairly encompasses cures to aging, cures to cancer, the common cold, etc. The specification is essentially silent as to how desired properties for which methods of screening and use have yet to be developed are to be practiced within the claimed invention

when the specification of the instant application does not set forth the starting materials or reaction conditions.

18. Applicant's representative presents argument at page 11 that:

> Applicant further contends that the screening of polypeptides expressed by mutagenized polynucleotides for desired properties is routine within the fields of biochemistry and molecular biology.

This argument has been fully considered and has not been found persuasive. Attention is directed to MPEP 2145.

> Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art.
> The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration.

19. For the above reasons, and in the absence of convincing evidence to the contrary, claims 16-39 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Claim Rejections - 35 USC § 102

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

21. Claims 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by GIBCO BRL Products & Reference Guide (1997; GIBCO).

22. For convenience, claims 21-23 are reproduced below.

21. (previously presented) A mutagenized polypeptide, having a predefined desired activity, encoded by the mutagenized polynucleotide produced by the method of claim 16 or 17.

22. (previously presented) A vector comprising a mutagenized polynucleotide produced by the method of claim 16 or 17.

23. (previously presented) A polypeptide comprising at least one sequence segment expressed from a mutagenized polynucleotide produced by the method of claim 16 or 17.

23. Claims 21-23 have been construed as being a product-by-process claim, which are considered for purposes of examination to be a product claim. Accordingly, a product produced by another process can anticipate the claimed product.

24. GIBCO disclose recombinant human Interleukin-1a as well as recombinant murine Interleukin-1B. As seen in the description of both products, they are expressed from transformed *E. coli.* Accordingly, the transformed bacteria are considered to meet the requirements of claim 22 in that a vector comprises a "mutagenized polynucleotide," and that the recombinant protein meets the limitations of claims 21 and 23 in that it has a predefined desired activity.

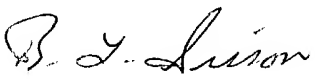
25. Accordingly, an in the absence of convincing evidence to the contrary, claims 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by GIBCO BRL Products & Reference Guide (1997; GIBCO).

Conclusion

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

28. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
17 November 2004